

REMARKS

Status of the Application

1. Claims 1-38 have been examined in this application in response to communications filed October 29, 2007.

Rejections under 35 USC § 103

3. **Claims 1-2, 4-12, 14-22, 24-27, 29-34 and 36-38** are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Number 6,496,804 to McEvoy in view of US Patent Application Publication 2005/0033639 to Myers and in further view of US Patent Number 5,832,449 to Cunningham (from the applicant's Information Disclosure Statement (IDS)).

4. **Claim 3** stands rejected under 35 U.S.C. 103(a) as being unpatentable over McEvoy in view of Myers and Cunningham as applied to Claim 2 above, and in further view of US Patent Number 5,666,490 to Gillings.

(B) As per claims 23, 28 and 35, these claims repeat features previously addressed in the rejection of claims 1-14 and are rejected on the same basis.

5. **Claim 13** stands rejected under 35 U.S.C. 103(a) as being unpatentable over McEvoy in view of Myers and Cunningham, as applied to Claim 1, above.

Applicant traverses each of the rejections and requests reconsideration.

Argument

Underlying the rejections in the examination report is the reliance upon McEvoy teaching a majority of the subject matter set forth in the independent claims. Applicant disagrees with these conclusions and respectfully requests reconsideration of the alleged teachings of McEvoy.

Claim 1 as amended and with emphasis added reads:

1. A method for distributing pharmaceutical drug samples, comprising a step of adjudicating a claim by a drug dispenser for the use of a token for a pharmaceutical drug sample at a claim adjudication system for adjudicating pharmacy benefit claims under patient drug plans, the token being distributed by a prescriber to permit the patient to obtain the pharmaceutical drug sample from the drug dispenser.

The examiner has concluded that McEvoy teaches, in terms of the language of claim 1, "a method for distributing pharmaceutical drug samples, comprising a step of adjudicating a claim by a drug dispenser for the use of a token for a pharmaceutical drug sample at a claim

adjudication system for adjudicating pharmacy benefit claims under patient drug plans. Support for such is alleged found at Col. 1, Ln. 51-58 and col. 4, Ln. 61-Col 5, Ln 5.

Applicant has carefully reviewed McEvoy and these cited sections in particular with a mind willing to understand. Even if McEvoy can be said to relate to any product, Applicant does not see any suggestion in McEvoy, whether explicit or implied, to adjudicate a coupon claim "at a claim adjudication system for adjudicating pharmacy benefit claims under patient drug plans". As McEvoy discusses the purchase of general products with coupons, there is no discussion in McEvoy of insurance, drug plans or insurance adjudication systems.

The support and reasons for the claim rejection are identical to those raised to the previous set of claims. Applicant requests that the examiner give the amendments full and fair consideration and point out with specificity where in McEvoy there is any discussion that could relate to utilizing a processing system as claimed.

Importantly, the pharmacy benefit claims and the associated claims adjudication system refer to a patient benefit claims under an applicable patient insurance plan. The claims adjudication system processes pharmacy benefit claims for patients according to their respective insurance drug plans. When combined, the cited references do not teach or suggest such a claims adjudication system. None of the systems therein relates to insurance claim processing at all.

In association with the dispensing of samples, the pharmacy presents a claim to the same claim adjudication system for pharmacy benefits (i.e. drug plan benefits) as it would submit a patient's normal claims for prescriptions. In this way, the sample distribution reimbursement operations and any data collection operations and value-added pharmacy services (e.g. as per claim 8 as originally filed, formulary management services and drug utilization review (DUR) services) can be provided in a manner that exists for prescribed drugs. As set forth in para [0008] of the application as filed:

In addition to claims adjudication services, the adjudication network may provide other value-added pharmacy benefit management services, such as drug utilization review for assuring that a patient receives an appropriate drug therapy based on current medical guidelines. Additional pharmacy benefit management services may include an option that directs the use of recommended lower cost drugs that have the same or similar therapeutic effects and disease management (formulary management) or other managed care methods for a chronic or acute condition

As McEvoy relates to processing mailing label coupons for general merchandise, it does not describe an insurance adjudication network that is configured to provide any of these additional benefits.

Claim 8 specifically claims selected additional services that may benefit users/participants in the method and system of the present invention. Claim 8 is rejected on the additional basis of Cunningham teaching formulary management and DUR services; yet, the reference to Cunningham in support of this allegation states:

To validate the presented product trial media, the pharmacy communicatively links the presented media to the central computing station via the pharmacy terminal. After making selected verifications, the central computing station validates the presented product trial media. Validation results in the pharmacy dispensing the pharmaceutical trial product identified by the presented media.

A fair reading of Cunningham by a person skilled in the art would not interpret this statement to describe either formulary management services or DUR services, as these terms would be understood by persons of ordinary skill in the art. The rejection is improperly founded.

In accordance with applicant's invention, the patient gets the drug but does not pay for it. The pharmacist gets reimbursed in a trusted manner as exists for the current distribution of drugs under prescription drug insurance plans. Data is collected by a system that already functions to do so. By integrating into the claims adjudication system, numerous technical issues need not be re-solved and few operational changes at the pharmacy are required. Patients also receive drugs that have not traveled through existing sample distribution channels and may receive additional services, particularly drug utilization review services, from the pharmacist that they would not otherwise be able to receive in association with the distribution of the drug sample.

In brief, none of the cited art and in particular McEvoy, Myers, Cunningham and Gillings teach or suggest using a claims adjudication system for adjudicating pharmacy benefit claims under patient drug plans to process a claim to distribute pharmaceutical drug samples.

The argument above may be applied to each of the claims of the present application and even though such claims may include additional patentable subject matter, for this reason alone applicant submits all of the claims are allowable.

The examiner has suggested that applicant consider amendments to describe benefits of the use of an adjudication system for insurance claims pharmacy benefit plans or features

discussed in an earlier telephonic examination and cautions that such amendments may lead to additional searches. Applicant submits that the present claims already distinguish over the cited references and that additional amendments to describe beneficial results are not required. Further, applicant submits that where the present claims do set forth additional features or benefits to patients and pharmacies, such as in original claim 8, this subject matter is not being considered.

Summary and Telephone Interview Request

Applicant submits that the Examiner's cited references neither alone, nor in combination, disclose the Applicant's invention as presently claimed. For all of the reasons set out above, Applicant respectfully submits that the application in its present form is in condition for allowance and action toward that goal is respectfully requested.

The Examiner is kindly invited to contact applicant's agent Jonathan Pollack at 416.862.5405 to discuss the foregoing prior to issuing any further office action.

Date: July 30, 2008

Respectfully submitted,

/Jonathan Pollack/

Jonathan Pollack

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